REMARKS

I. Status of Claims

Upon entry of this amendment, claims 6-8 and 23-28 are pending. Claims 6-8 and 23-24 have been amended solely to improve their form. No new matter was added by this amendment. Applicants reserve the right to prosecute the canceled claims in divisional or continuation applications that relate to this application. Entry of this amendment is respectfully requested.

II. Formalities

The Examiner states that the information disclosure statement filed April 9, 2007 failed to comply with the provisions of 37 C.F.R. §§ 1.97 and 1.98 and M.P.E.P. § 609 because a publication date was not provided for reference AW. Applicants thank the Examiner for placing reference AW in the application file and for considering the remaining references in the information disclosure statement. To the best of the undersigned's knowledge, the cited reference was never published so no publication date is available.

III. Claims Rejected Under 35 U.S.C. § 112, second paragraph

Claims 6-8 and 25-28 are rejected under 35 U.S.C. 112, second paragraph for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Specifically, the Examiner states that the terms "a test colon cell sample" and "a colon cell" lack clarity because it is unclear as to what these phrases are referring.

Claims 7-8 and 25-28 are also rejected under 35 U.S.C. 112, second paragraph for allegedly lacking antecedent basis for the term "expression of the gene." Applicants traverse in view of the present claim amendments.

Applicants have amended the rejected claims to clarify the wording of claims 6-8 and 25-28. Applicants submit that the claim amendments obviate the rejection of these claims. Reconsideration and withdrawal are respectfully requested.

IV. Claims Rejected Under 35 U.S.C. § 103

Claims 6-8 and 23-28 are rejected under 35 U.S.C. 103(a) as being allegedly unpatentable over Au-Young *et al.* (US Patent No. 6,500,938 B1; hereinafter "Au Young") in view of Xu *et al.* (U.S. Patent Publication No. 2002/0182191 A1; hereinafter "Xu"). The Examiner asserts that Au-Young describes a composition comprising at least a portion of a sequence selected from the group consisting of SEQ ID NOs: 1-1490, where SEQ ID NO: 249 is identical to SEQ ID NO: 22 of the instant claim 6. The Examiner further asserts that Au-Young describes using the composition as a hybridizable array element in a microarray for monitoring the expression of a plurality of target polynucleotides and in the diagnosis of cancer by comparing expression levels of gene products in test and control colon samples, which is indicative of a cancerous state in the test sample. The Examiner acknowledges that Au-Young does not describe at least 2-fold, 2.5-fold, or 5-fold increases in expression levels, contacting a probe specific for a polypeptide, or a probe that is a detectably labeled antibody. The Examiner states that Xu describes methods for diagnosing colon cancer by detecting a colon tumor protein or mRNA. The Examiner concludes that it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify the method of Au-Young by detecting the at least two fold increase to determine the presence of cancer and detecting via antibody binding as stated by Xu. The Examiner alleges that the motivation to do so would have been to improve methods for detecting since colon cancer remains difficult to diagnose and early detection is important.

Applicants respectfully traverse the Examiner's rejection and its supporting remarks. The cited references fail to teach a method that is within the scope of the pending claims. Au-Young merely presents a list of sequences that were isolated from colon tumor and non-tumor tissue at a specific time. At best, the sequences can only be characterized as a snapshot of genes expressed at a given moment in the tissue, regardless of whether the genes have any correlation with colon cancer. Au-Young provides no specific disclosure of a correlation between the sequences and colon

cancer. Moreover, Au-Young does not provide any information relating to the level of expression of its sequences. Accordingly, Au-Young makes an inappropriate association between the sequences and cancer without any data or experiments to show a link between the two. Without any characterization of the sequences and any investigation of their link to colon cancer, Au-Young inappropriately concludes that such sequences can be used in the diagnosis and treatment of colon cancer. See col. 2, 87, and 90. Au-Young provides no guidance whatsoever that would suggest to the skilled person which of its sequences is associated with colon cancer. Given the number sequences that are described for colon tissue and the lack of any data linking them to colon cancer, there can be no reasonable expectation that a skilled person could successfully select one of the sequences and use it to assess a cancerous phenotype in a colon cell by measuring its gene expression.

Xu fails to cure the deficiencies of Au-Young because Xu fails to describe the sequence defined by SEQ ID NO: 22, as required in the rejected claims. Accordingly, the cited references cannot provide the skilled person with any reasonable expectation of successfully performing the claimed methods.

By contrast, the methods of the claimed invention can be used to assess a cancerous phenotype in a colon cell by measuring gene expression in the claimed sequence because Applicants have established a correlation between the claimed sequence and colon cancer by showing increased gene expression of the sequence in tumorigenic colon cancer cells. Applicants isolated mRNA from samples of cancerous colon tissue obtained from patients suffering from colon cancer. The mRNA was used to probe microarrays to identify sequences that show increased levels of expression in colon cancer cells as compared to normal colon cells. The claimed sequence showed increased expression in colon cancer cells as compared to normal colon cells. See Example 2 (paragraphs 158-171) and Table 6 (page 122) of the present specification. The increased expression of the claimed sequence in the colon cancer cells was further analyzed using antisense technology to confirm the role and function of the claimed sequence in tumorigenesis (e.g., in promoting a metastatic phenotype). See Example 3 (paragraphs 172-182, and Table 7 (page 157) of the present specification.

For the foregoing reasons, Applicants respectfully request that the Examiner withdraw the rejection of claims 6-8 and 23-28 under 35 U.S.C. 103(a) as the cited references cannot provide the skilled person with any reasonable expectation of successfully performing the claimed methods.

V. Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. **223002105901**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

In addition, please direct all further communications in this application to:
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Dated: June 20, 2008

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